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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/809,621 06/02/97 IDA

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EXAMINER

CANELLA, K

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

09/18/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/809,621

Applicant(s)

Ida et al

Examiner

Karen Canella

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-21 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

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Response to Amendment

1. Claims 13 and 14 have been amended. Claims 17-21 have been added.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

New Grounds of Rejection

3. Claims 13, 14 and 16-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for treating a bone disorder in a patient having an osteoclast-related bone disorder characterized by osteolysis as a result of stimulated osteoclast activity, does not reasonably provide enablement for a method of treating a bone disorder in a patient having all other metabolic disorders other than those related to an increased production of parathyroid-hormone related peptide, osteomalacia, hormonal disorders characterized by an overproduction of gonadal hormones, or a method of treating a patient having a bone disorder mediated by prostate cancer or non-metastatic colon cancer or cancers of the digestive tract. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The specification provides data to support the use of interferons beta to inhibit bone resorption and promote mineralization in a murine model of menopausal osteoporosis. It is well known in the art that menopausal osteoporosis is a result of increased levels of Il-6, a cytokine recognized in the activation and recruitment of osteoclasts (Manolagas et al, Ciba foundation Symposium, 1995, Vol. 191, pp. 187-196). Menopause can be considered a hormonal disorder characterized by an underproduction of gonadal hormones. However, there are no teachings in the specification providing evidence that the administration of INF-b would be efficacious in conditions characterized by hormonal disorders characterized by an increase in gonadal hormones, mediated by an underproduction of Il-6 and lack of normal osteoclastic activity. As it is taught in the instant specification, INF-B inhibits osteoclast activity to result in increased bone density. One of

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skill in the art would not know how to use the instant method for diseases which would require increased osteoclast activity and/or decreased osteoblast activity. It is recognized in the art that many metastatic cancers, with the notable exception of metastatic prostate cancer (Goltzman et al, Cancer, 2000, Vol. 88, suppl., pp. 2903-2908), activate osteolysis by a mechanisms which involves upregulation of osteoclast activating cytokines, either systemically or local near metastatic lesions. Goltzman et al teaches that the predominant skeletal response to prostate carcinoma is osteogenesis and resulting osteomalacia versus an osteolytic response. One of skill in the art would not know how to use the instant method to treat bone disease induced by prostate cancer as treatment of osteogenesis and osteomalacia would require increased osteoclast activity and/or decreased osteoblast activity. Further, there are no teaching in the specification or any art of record linking colon cancer, metastatic colon cancer, cancers of the digestive tract and metastatic cancers of the digestive tract. Thus, one of skill in the art would not know how to apply the instant method to the treatment of bone diseases arising from the presence of colon cancers or cancers of the digestive system.

4. Claims 13- 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manolagus (Bone, 1995, 2) Suppl., 63S-67S) in view of Zawatzky et al (Journal of Virology, 1991, Vol. 65, pp. 4839-4846). Claims 13 and 20 are drawn in part to treating a patient having an osteoclast related bone disorder by the administration of INF-B. Claims 14 and 21 embody osteoporosis and hormonal disorders as osteoclast related bone disorders. Mangolas teaches that the osteoclast-related bone disorders of osteoporosis are related to loss of gonadal function and concomitant Il-6 production. Mangolas teaches that this Il-6 production activated the formation of osteoclasts and results in bone resorption. . Zawatzky et al teaches that INF-B is a negative regulator of Il-6. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to treat osteoporosis or bone disorders mediated by a decrease in gonadal hormones by the administration of INF-B. One of ordinary skill in the art would have been

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would have been motivated to do so with a reasonable expectation of success by the teachings of Zawatzky et al on the negative regulatory effect INF-B exerts on the production of Il-6 and the correlation of elevated Il-6 levels with bone resorption as taught by Mangolas.

5. All other rejections and objections as stated in Paper No. 23 are withdrawn.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.
Patent Examiner, Group 1642
August 27, 2001


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